UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS** **Subcategory Case No. 06-11337**
THIS DOCUMENT RELATES TO: *State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc. et al.*, Civil Action No. 03-11226-PBS	**Hon. Patti B. Saris**

DEFENDANTS' JOINT STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF THEIR MOTIONS FOR PARTIAL SUMMARY JUDGMENT

Pursuant to Local Rule 56.1, Defendants Mylan Inc., Mylan Pharmaceuticals Inc., Dey, Inc., Dey, L.P., and Sandoz Inc. (collectively, "Defendants") submit this joint statement of the material facts of record as to which there is no genuine issue to be tried in support of their Joint Motion for Partial Summary Judgment.

I. THE MEDICAID PROGRAM

1. The Medicaid program was signed into law in 1965 as part of Title XIX of the Social Security Act and is a joint federal-state program that provides medical assistance to financially needy patients. *See* 42 U.S.C.A. § 1396-1 (2009).

2. The Medicaid program is jointly funded by states and the federal government. The federal government pays for a share of each state's Medicaid program expenditures which ranges from 50% to 83%. *See* 42 U.S.C.A. § 1396d(b) (2009).

3. In 1987, CMS, then known as the Health Care Financing Administration ("HCFA"), after a Task Force report and recommendation, adopted regulations governing reimbursement payments for healthcare services provided by state Medicaid programs, including

payments for drugs. *See* 42 C.F.R §§ 447.301 to 447.333. Those regulations remained in effect and did not substantially change from January 1, 1994 to December 31, 2004 (the "Relevant Time Period").

4. CMS provides individual states substantial discretion in designing their Medicaid programs. *See* 42 C.F.R § 447.502 (2009); 42 C.F.R § 447.302 (2009); 42 C.F.R § 447.304 (2009); 42 C.F.R § 447.512 (2009); 42 C.F.R § 447.514 (2009); 42 C.F.R § 447.518 (2009).

5. State Medicaid agencies must act in accordance with their State Plan, which CMS reviews and approves annually. *See* 42 C.F.R § 447.201 (2009); *see* 42 C.F.R § 447.518 (2009).

6. However, within the broad federal requirements set by CMS, states have considerable flexibility in designing their State Plans. (Robben Decl., Ex. 2 at 431:4-9; Robben Decl., Ex. 3 at HHC002-0565.)

7. Bruce Vladeck, Administrator of CMS from 1993 to 1997, testified that states had leeway to be able to determine the specific ingredient reimbursement basis that they wanted, as long as it was acceptable to the federal government, and the federal government approved a variety of reimbursement methods that were consistent to federal law. (Robben Decl., Ex. 4 at 433:8-449:12.)

8. Mr. Vladeck testified as follows:

> A. HCFA approved state plans that paid on some basis relative to AWP, because that's what the statute provided for.
>
> Q. And in doing that you were approving plans that had the spread built into the reimbursement methodology. Right?
>
> MS. BROOKER: Objection. Form.

> A. Again, I would say that had a spread built into the reimbursement methodology.
>
> Q. Fine. But you also had one state, at least, that had no spread. Right?
>
> MS. BROOKER: Objection. Form.
>
> MR. BREEN: Objection. Form.
>
> A. Yes, that's correct.

(Robben Decl., Ex. 4 at 448:21-449:12.)

9. Thomas Scully, Administrator of CMS from 2001 to January 2004, testified that it was CMS's policy to let the states make their own determination of what levels to reimburse providers at, and that it was up to the states' discretion whether they decided to reimburse at, for example, AWP minus 10% when CMS and the state knew that average actual acquisition cost was more like AWP minus 40%. (Robben Decl., Ex. 5 at 209:11-210:15.)

"In the Aggregate"

10. For multiple source drugs subject to an upper limit established by HCFA, the 1987 regulations limited payment in the aggregate, across all drugs, to the amount that would result from the application of the specific limits established by HCFA plus a reasonable dispensing fee. (Robben Decl., Ex. 6.)

11. For all "other drugs" not subject to a Federal Upper Limit ("FUL"), a state agency's payment "must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the (1) EAC plus reasonable dispensing fees established by the agency; or (2) Providers' usual and customary charges to the general public." *See* 42 C.F.R. § 447.512(b) (2009).

12. The regulations define "estimated acquisition cost" to be a state agency's "best estimate of the price generally and currently paid by providers for a drug marketed or sold

by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." *See* 42 C.F.R. § 447.502 (2009).

Access to Care

13. A state agency's reimbursement methodologies are subject to an access constraint: "The agency's payments must be sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population." *See* 42 C.F.R. § 447.204 (2009).

14. Accordingly, state Medicaid agency personnel attempt to balance at least two competing goals when making policy decisions to set reimbursement rates: 1) achieve sufficient access to quality health care for the enrollees and 2) administer the program within the budget constraints imposed by the state legislature. (*See* Joint SOF *infra* at ¶¶ 52, 56, 57; *see also* Robben Decl., Ex. 7 at 108:3-109:13; Robben Decl., Ex. 8 at 307:13-308:5; Robben Decl., Ex. 9 at 464:2-465:7; Robben Decl., Ex. 10 at 49:10-51:18.)

II. THE MEDI-CAL PROGRAM

15. California's Medicaid program is known as Medi-Cal. (Robben Decl., Ex. 11 at 184:2-9.) It is administered by the California Department of Health Care Services, formerly known as the California Department of Health Services. *Id.* (Hereinafter, the California Department of Health Care Services, formerly known as the California Department of Health Services, shall be referred to as "DHS").

16. Throughout the relevant time period, the Medi-Cal program has provided coverage for prescription drugs. (Robben Decl., Ex. 1 at ¶ 26.)

17. Single-source, or brand name, drugs account for approximately 80% of the Medi-Cal program's expenditures for drugs. Multi-source, or generic, drugs account for only

approximately 20% of the Medi-Cal program's total expenditures for drugs. (Robben Decl., Ex. 11 at 192:14-193:12.)

18. Throughout the relevant time period, Medi-Cal reimbursed pharmacists and other Medicaid providers who dispensed the Subject Drugs at the lower of Estimated Acquisition Cost ("EAC"), the Federal Upper Limit ("FUL"), the Maximum Allowable Ingredient Cost ("MAIC"), or the charge submitted by the provider. (Robben Decl., Ex. 13.)

19. From January 1, 1994 to November 30, 2002, EAC was defined in regulations as Average Wholesale Price ("AWP") minus five percent. From December 1, 2002 to August 31, 2004, EAC was defined in regulations as AWP minus ten percent. From September 1, 2004 to the present, EAC has been defined as AWP minus 17 percent. (Robben Decl., Ex. 13.)

20. Throughout the relevant time period, California has defined "AWP" as "the price for a drug product listed for a standard package in the Department's primary price reference source." *See* 22 CCR § 51513.

21. From January 1, 1994 to August 31, 2004, California paid a dispensing fee of $4.05. (Robben Decl., Ex. 13.) From September 1, 2004 to the present, California has paid a dispensing fee of $7.25 ($8.00 for drugs administered by long-term care facilities.) *Id.*

III. CALIFORNIA'S UNDERSTANDING OF AWP AND REIMBURSEMENT METHODOLOGIES DURING THE RELEVANT TIME PERIOD

22. Through both independent and government-sponsored studies, California has understood since well before the relevant time period that published AWPs, particularly those for generic drugs, did not reflect providers' actual discounted acquisition costs for drugs. (*See* Joint SOF *infra* at ¶¶ 23-40.)

23. In 1977, the California Department of Finance issued a report entitled "Medi-Cal Drug Price Controls, A Staff Reference Report" (the "1977 Report"). (Robben Decl., Ex. 14.) The 1977 Report examined various possible cost-control measures for Medi-Cal's prescription drug benefit. The 1977 Report documented that pharmacies could purchase drugs at significant discounts below AWP from manufacturers:

> Manufacturers' list prices to wholesalers and retailers, based upon inspection of the Red Book, appear to range from 14 percent below AWP from some manufacturers to 22 percent for others.
>
> Average Wholesale Price less these published discounts is the maximum price the pharmacist can expect to pay if he buys direct from the manufacturer. The range of discounts below AWP is in fact very wide and apt to change rapidly. Inspection of manufacturers' price lists for some items show discounts larger than those that appear in the Red Book by taking into account not only quantity per retail package, but number of packages per order. Other forms of discount include periodic rebates, extra goods given to the pharmacy by the manufacturer's representative, returned goods policy used to return slow-moving merchandise in addition to outdated goods, and extended dating of receivables. Special deals are offered intermittently and in certain areas but not others. Some such discounts reflect themselves in invoice prices; others do not.

Id. at 4. The report found that similar – though not as steep – discounts were available through wholesalers:

> Wholesalers' discounts to most pharmacies in California appear to range from 8 to 12 percent below AWP. … These discounts normally apply, not on an item-by-item basis, but to all purchases made during a month or other span of time. … These discounts usually do not appear on invoices. The discount serves as both a volume and cash discount.

Id. at 4-6. On a whole, the report concluded that "[t]he range of discounts among pharmacies is unknown but probably is from 8 to 25 percent or more…" *Id.* at 6. The Report noted that, at the time, EAC for most drugs was an undiscounted AWP and that "[t]he actual acquisition cost of individual pharmacies has no bearing upon the payment Medi-Cal makes." *Id.* at 23. The 1977

Report also noted that "[s]ome manufacturers maximize pharmacy earnings from Medi-Cal by maximizing the spread between the price charged Medi-Cal (usually based on small quantities) and that paid by pharmacies (often a lower price based on large quantities)." *Id.* at 29. However, the Report recognized that the margins providers realized compensated for inadequate dispensing fees: "Prior to the new EAC controls of March 6, 1977 the margin between AWP and pharmacies' actual acquisition cost served to offset a fee level which many pharmacists believed to be inadequate." *Id.* at 23.

24. In 1985, HCFA conducted a California-focused study comparing published AWPs to actual acquisition costs available to pharmacists throughout the state. (Robben Decl., Ex. 15.) HCFA published its findings in a report entitled "EAC Survey Report, California Medi-Cal Program, EAC Patrol Initiative". *Id.* The report noted that "AWPs are not determined by surveying market transactions and thus do not accurately reflect prices pharmacists pay for drug products." *Id.* at 2. The report also noted that, at the time, California's EAC was calculated using an undiscounted AWP. *Id.* at 4. The report concluded that California pharmacists acquired drugs at an average of 16.63 percent below AWP. *Id.* at 6. The report also found that California pharmacists purchased generic drugs at an average of 22.14 percent below AWP. *Id.* at 7.

25. In a February 4, 1986 letter, John Rodriguez, at the time the Deputy Director of Medical Care Services at DHS, acknowledged receipt of this report. (Robben Decl., Ex. 16.) In the letter, Mr. Rodriguez expressed concern about using the findings in the report to adjust California's EAC. In particular, Mr. Rodriguez noted:

> [W]e would like to remind HCFA that successfully "tightening up" our EAC program will concomitantly result in enormous pressure for California's Medi-Cal program to upgrade the dispensing fee. This is exactly what occurred when we originally implemented our

> EAC program. Such a development may well result in no significant change in overall drug costs. If, in fact, costs are only shifted, is a change in federal regulations or more aggressive enforcement of existing EAC regulations really cost effective?

Id.

26. When California adopted HCFA's 1987 FUL regulations, it issued a statement of reasons supporting its adoption of the regulations. (Robben Decl., Ex. 17.) In the addendum to the final statement of reasons, in response to complaints that FULs may adversely impact small business, California noted that the FUL regulations would actually benefit small businesses, while at the same time saving California money, by encouraging the use of low cost generics:

> The regulation encourages pharmacists to select from among available alternatives, the drug product which meets the patient's needs and is available within the upper limit. Lower priced generic brands frequently carry a higher margin of profit in comparison to the more costly name brand drug products they compete with. This has the effect of increasing the actual net profit dollars on a smaller gross sale.

Id. at addendum 2. To illustrate the point, the addendum compared the reimbursement for a brand drug, Mellaril, with an AWP of $28.32, and FUL of $17.48, and an actual purchase price of $26.06 to the generic version of the drug, which had an AWP of $10.90, and an actual purchase price of $5.23. *Id.* at addendum 3. Because of the FUL, the addendum noted that dispensing the brand drug would result in a net loss to the provider of $12.62, while dispensing the generic would result in a net profit of $5.67. *Id.* The addendum concluded that the FUL, when combined with the "spread" between the AWP and actual purchase price for the generic drug, benefited both California and the provider:

> Not only did the pharmacist increase his margin by $3.40 when dispensing the generic drug product over the brand name product; but, by placing an upper limit of reimbursement, Medi-Cal saved

> $15.15, which is more than 50% of the reimbursement amount for the brand name product.

Id. at addendum 4. In preparing the final statement of reasons and the addendum, California relied on several wholesaler catalogs, including a catalog of Geneva Inc. drugs. *Id.* at 2.

27. In 1989, the Office of Inspector General for the United States Department of Health and Human Services ("HHS-OIG") issued a report entitled "Use of Average Wholesale Prices in Reimbursing Pharmacies Participating In Medicaid and the Medicare Prescription Drug Program" (the "1989 HHS-OIG Report"). (Robben Decl., Ex. 18.) The report detailed a survey conducted by the HHS-OIG comparing AWPs published in Blue Book and Medi-Span to prices available to pharmacies through national wholesalers. *Id.* at 2. The report found that the average discount off of AWP for all drugs was approximately 15.5 percent, and for multi-source or generic drugs in particular was 18.2 percent. *Id.* at 3. The report found that prices in one wholesaler's catalog were on average more than 30 percent below AWP. *Id.* The report quoted a wholesaler representative stating "AWP is a meaningless figure" and a Pennsylvania Medicaid official saying that AWP "… just doesn't mean anything. It has no connection to what pharmacies really purchase the drugs for." *Id.* at 3-4.

28. In 1991, the Auditor General for the State of California issued a report entitled "How Medi-Cal and Other Health Care Providers Manage Their Pharmaceutical Expenditures." (Robben Decl., Ex. 19.) The Auditor's report cited to the 1989 HHS-OIG Report, noting that the report found that pharmacies were purchasing drugs, on average, at15.5 percent below AWP and that the report "concluded that the AWP was not a meaningful payment level and that it should not be used for making reimbursements." *Id.* at 27. The report goes on to note that, in September of 1989, in response to guidance from HCFA that state Medicaid programs must discount off of AWP for EAC calculations, DHS adopted regulations setting

reimbursement at AWP minus five percent for drugs not reimbursed on the basis of direct price. *Id.*

29. In 1994 and 1995, the HHS-OIG conducted a California-focused survey of pharmacy acquisition costs for Medi-Cal providers. (Robben Decl., Ex. 20; Ex. 21; Ex. 22.) DHS employees Douglas Hillblom, Allen Fung, and Roy Takeuchi assisted in the survey. (Robben Decl., Ex. 20 at App. 4.)

30. In August of 1994, HHS-OIG held a meeting in Richmond, Virginia to discuss the survey and enlist the assistance of various state Medicaid programs. (Robben Decl., Ex. 21.) Allen Fung attended the meeting on behalf of the Medi-Cal program. *Id.* State Medicaid officials at the meeting expressed concern that the review was limited to one aspect of pharmacy reimbursement and indicated that any effort to lower reimbursement for pharmacists' acquisition costs should also take into account dispensing fee payments. *Id.*

31. In September of 1995, HHS-OIG held a second meeting in Richmond, Virginia to report on the survey's findings. (Robben Decl., Ex. 23.) Douglas Hillblom attended this meeting on behalf of the Medi-Cal program. *Id.* The state Medicaid officials at the meeting indicated that the results of the survey were in line with what they anticipated. *Id.*

32. In May of 1996, HHS-OIG published the results of the California-focused survey in a report entitled "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the California Department of Health Services" (A-06-95-00062) (the "1996 HHS-OIG Report"). (Robben Decl., Ex. 20.) The 1996 HHS-OIG Report examined over 2600 pharmacy invoices from across the state and found that pharmacists' invoice prices for brand-name or single source drugs were, on average, 17.5 percent below published AWPs and that invoice prices for generic or multi-source drugs were, on average, 41.4

percent below AWP. *Id.* at i. In his response to the report, John Rodriguez hoped that the report would "substantiate DHS' position that current drug ingredient cost reimbursement by the Medi-Cal program does not reflect actual purchasing activity of California pharmacies." *Id.* at App. 4.

33. In 1996, the California legislature considered revising Medi-Cal's EAC calculation from AWP minus five percent to AWP minus ten percent or Wholesale Acquisition Cost ("WAC") plus seven percent. (Robben Decl., Ex. 24; Ex. 25 at 143:15-147:18.) In response, DHS prepared a document assessing the fiscal impact of the change and weighing its pros and cons. (Robben Decl., Ex. 24.) The document listed the following as the "Pros" to the proposed change:

- Reduces drug expenditures by reducing ingredient cost reimbursement to make it more consistent with the actual acquisition cost of drugs, and other third party payers.
- Would result in General Fund savings.

Id. The document also listed the following as the "Cons" to the proposed change:

- Will be opposed by pharmacy providers just as they opposed a previous legislative proposal on this issue.
- Will undermine working relationship between Department of Health Services and the California Pharmacists Association (CPhA) in efforts to develop a regulatory solution that reduces ingredient costs while recognizing other inequities in the reimbursement policies.
- Some pharmacy providers will stop providing services to Medi-Cal beneficiaries because of the reduced payment.

Id. Douglas Hillblom, a Pharmacy Consultant with DHS from 1995 to 2000, testified that the "other inequities" referenced in the second bullet point under "Cons" included an inadequate

dispensing fee. (Robben Decl., Ex. 25 at 39:12-40:2; 157:4-158:12.) Although it was considered, this methodology was never adopted. *See supra* at ¶ 19-21.

34. Vic Walker, a Pharmacy Consultant with DHS since 1988, indicated that DHS had access to WACs from First DataBank at the time this proposal was under consideration. (Robben Decl., Ex. 26 at 76:1-77:22.)

35. In 1999, Vic Walker prepared an analysis of a similar proposal. (Robben Decl., Ex. 27.) His analysis described the proposal as follows:

> This proposal changes the method by which pharmacy drug acquisition costs are reimbursed by replacing Average Wholesale Price minus 5% (AWP-5%) and the Direct Price reimbursement elements in the formula with AWP minus X% or Wholesale Acquisition Cost (WAC) plus Y percent, which is lower, on a drug-by-drug basis. This would more closely approximate actual acquisition costs of drugs by pharmacies.

Id. Mr. Walker's analysis noted the California-focused 1996 HHS-OIG Report. *Id.* It also noted that it would be advisable to implement the change through legislation, rather than administrative rule making:

> This change *can* be implemented through regulation, but the Department does not believe it can sustain the legal challenges to the regulations that will be brought to bear by its opponents. The most certain way to implement a new reimbursement schedule is through legislation.

Id. The analysis also noted that political pressure from lobbying groups had blocked implementation of similar measures in the past:

> This identical proposal has been made almost every year since the early 1990s, but has been fought to a standstill in every instance by the effective lobbying efforts of the pharmacy provider organizations and beneficiary advocacy organizations. The pharmacy provider organizations oppose these changes because it would result in reduced reimbursement. The beneficiary advocacy organizations oppose them because they might result in reduced pharmacy provider participation.

Id. This proposal, like the previous one, was never adopted. *See supra* at ¶ 19-22.

36. In 2000, the California legislature was considering a bill, AB 1915, that would lower Medi-Cal's pharmacy reimbursement rate from AWP minus five percent to AWP minus 15 percent. (Robben Decl., Ex. 28 at 113:1-19; Ex. 29.) In response to the bill, DHS prepared a bill analysis recommending that AB 1915 be opposed. (Robben Decl., Ex. 29.) In the analysis, DHS raised the concern that a decrease in the reimbursement rate could drive providers out of the program, creating serious access issues:

> Reducing the Medi-Cal EAC for drugs with AWP minus 5 percent to AWP minus 15 percent would not be merited without first taking steps to determine an appropriate rate of reimbursement. Federal law requires that the state assure that "…payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers…" [Social Security Act Section 1902(a)(30)(A)] which can best be demonstrated through performance of a proper rate study.
>
> If the proposed AWP minus 15 percent were to be implemented, together with the current direct price component, California would be last in drug ingredient cost pharmacy reimbursement when compared to other "AWP minus" states. At this point, Medi-Cal may suffer a serious patient access problem as providers disenroll from Medi-Cal rather than accept the reduced payment.

Id. at 2. AB 1915 was never enacted. *See supra* at ¶ 19.

37. At their depositions, several Medi-Cal officials testified that they have understood for a long time that AWP was not representative of actual prices paid.

38. Kevin Gorospe, Chief of the Medi-Cal Pharmacy Policy Unit at DHS since 2000, testified as follows:

> Q. …You understood that variation -- Sometime in the late nineties you understood that variations existed between how Medicaid was reimbursing for drugs and the actual pharmacy acquisition costs for drugs?
>
> A. Yes.

(Robben Decl., Ex. 30 at 503:13-18.) Mr. Gorospe also acknowledged that prices for generic drugs were generally significantly more than 20 percent below AWP:

> Q. Did you have that understanding also going back to the late nineties, that AWP minus 20 percent is significantly higher than pharmacy acquisition costs for generic drugs?
>
> A. Yes.
>
> …
>
> Q … So was it your understanding to the extent you recall this proposal that the reimbursement rate of AWP minus 20 percent was made knowing that reimbursement on that basis would be significantly higher than acquisition costs for generic drugs?
>
> A. Yes.

(Robben Decl., Ex. 30 at 594:7-11; 594:21-595:5.)

39. Len Terra, Mr. Gorospe's predecessor, agreed that AWP did not reflect prices actually paid:

> Q. Would you have agreed in 1985 that AWP was not a reliable predictor of the price pharmacists actually pay for drugs?
>
> A. I probably would have agreed to that, but I would not have necessarily been privy to this type of information. I am not aware of, you know, being aware of this specific information, but it was generally known in the pharmacist industry that AWP did not reflect actual acquisition costs by pharmacists.

(Robben Decl., Ex. 31 at 107:1-11.)

40. Vic Walker indicated that he understood since 1996 that Medi-Cal's EAC calculation was higher than pharmacists' acquisition costs:

> Q. And was there a time after California implemented the AWP-5 percent reimbursement that you reached an understanding that reimbursement based on AWP-5 percent was in excess of pharmacies' actual acquisition cost?
>
> A. I -- at some point I arrived at that conclusion. I don't know when.

Q. It was before this report was issued though; correct?

A. Yes.

Q. Was it well before this report was issued?

A. Well, we have evidence in 1996 I was thinking that way.

(Robben Decl., Ex. 26 at 146:12-147:3.)

IV. THE MYERS & STAUFFER REPORTS

41. In 1999, the California legislature required DHS to perform a study of Medi-Cal provider acquisition costs and dispensing costs for pharmaceutical products. (Robben Decl., Ex. 32 at 227:13-18.) DHS commissioned Myers and Stauffer LC to conduct the study. *Id.* at 227:19-228:3.

42. In June of 2002, Myers and Stauffer issued two reports detailing the results of its study. (Robben Decl., Ex. 32 at 227:19-228:22; Ex. 33; Ex. 34.)

43. One report, entitled "A Survey of Acquisition Costs of Pharmaceuticals in the State of California," examined pharmacists actual acquisition costs for the top 2,000 drugs as measured by Medi-Cal expenditures. (Robben Decl., Ex. 34 at 3.) The report examined invoices from over 2,000 Medi-Cal providers. *Id.*

44. According to the report, pharmacists could acquire single source drugs at an average of 82.8 percent of AWP. (Robben Decl., Ex. 34 at 4) The report also found that pharmacists could acquire multi-source drugs without a FUL for an average of 56.6 percent of AWP. *Id.* Finally, the report concluded that pharmacists could acquire multi-source drugs with a FUL for an average of 12.7 percent of AWP and 38.7 percent of the FUL. *Id.*

45. The report also contained lists comparing average actual acquisition costs to published AWPs for the top 200 multi-source products without a FUL and the top 200 multi-source products with a FUL. (Robben Decl., Ex. 34 at Exs. 5 & 6.) Included on these lists are 3

of the Dey subject NDCs, 31 of the Mylan NDCs and 44 Sandoz NDCs. *Id.* The chart below sets forth examples comparing the average actual acquisition costs and published AWPs for certain of the Subject Drugs, as well as the "spreads" between them:

Drug/NDC	**Average actual acquisition cost per unit`**	**Published AWP per unit**	**Spread**
Mylan's cimetidine 00378037205	$0.05	$1.61	3055%
Mylan's diphenoxylate/atropine 00378041510	$0.09	$0.48	419%
Dey's ipratropium 49502068503	$0.21	$0.71	238%
Dey's albuterol sulfate 49502069703	$0.07	$0.40	471%
Sandoz' Amiodarone HCL 00781120360	$0.57	$3.13	447%
Sandoz' Atenolol 00781150701	$0.03	$1.04	3836%

46. Not surprisingly, the report concluded that California's EAC calculation at the time, AWP minus five percent, paid providers considerably more than their actual acquisition cost for drugs:

> Findings from this study indicate that the current pharmacy ingredient reimbursement rate of AWP less 5% provides payments in excess of the costs actually incurred by California pharmacies in acquiring pharmaceutical products for Medi-Cal recipients. In fact, the acquisition cost study findings indicate that for a "typical" prescription, a pharmacy's margin on ingredient reimbursement is approximately $10.

(Robben Decl., Ex. 34 at 4-5.) However, the report warned that the ingredient cost could be assessed without also considering the dispensing fee:

> These margins on ingredient cost must be considered in tandem with an analysis of pharmacy dispensing cost and dispensing fee reimbursement.

Id. at 5.

47. The second report, entitled "Study of Medi-Cal Pharmacy Reimbursement," examined Medi-Cal pharmacy providers' costs to dispense drugs. (Robben Decl., Ex. 33.) The report found that the average cost of dispensing drugs weighted by Medi-Cal volume was $8.69. *Id.* at 26. Excluding intravenous and compounded drugs, the report found that average cost of dispensing weighted by Medi-Cal volume was $7.21. *Id.* at 28. Even excluding intravenous drugs, the average cost of dispensing was more than $3.00 higher than the $4.05 dispensing fee then paid by California.

48. As part of the report, Myers & Stauffer calculated the total average cost to the pharmacist to dispense the drug (including the pharmacist's cost to acquire the drug and the pharmacist's cost to dispense the drug), the average reimbursement payment by Medi-Cal (including the ingredient cost reimbursement and the dispensing fee), and the average margin for various categories of drugs:

	Average cost	**Average Payment**	**Average Margin**	**Percent Margin**
Brand drugs	$120.36	$133.14	$12.78	9.6%
Generic drugs without FULs	$28.87	$38.34	$9.47	24.7%
Generic drugs with FULs	$10.46	$11.73	$1.27	10.9%

(Robben Decl., Ex. 33 at 50.)

49. Both reports were provided to the California legislature and would have been considered by them in making any determinations regarding pharmacy reimbursement. (Robben Decl., Ex. 32 at 229:1-230:7.)

V. CALIFORNIA'S CHANGES TO ITS REIMBURSEMENT METHODOLOGY AFTER THE MYERS & STAUFFER REPORT

50. As set forth above, California adjusted the manner in which it calculated EAC twice after the Myers & Stauffer report was issued.

51. In response to the legislation enacting the change from AWP minus five percent to AWP minus ten percent, DHS prepared an enrolled bill report that was signed on September 17, 2002. (Robben Decl., Ex. 35.) Enrolled bill reports are used by DHS to make recommendations to the Governor as to whether to sign or veto legislation passed by the California legislature. (Robben Decl., Ex. 32 at 67:1-12.)

52. In discussing the change from AWP minus five percent to AWP minus ten percent, the report notes:

> It is often noted that Medi-Cal's rate of AWP-5% is higher than other third-party payers, both in the private and public sectors. Various reviews of pharmacy purchasing indicate that brand name drugs are purchased at approximately AWP-15% to 17% and generic drugs can be purchased at AWP-40% to 50%. With this in mind, the original May Revision proposed deep cuts in the ingredient cost rate to AWP-10% for brand drugs and AWP-40% for generic drugs. This type of change, however, does not take into account the overall reimbursement (professional fee) rate. The pharmacy industry has indicated that the average cost of dispensing a prescription, in California, ranges from $6 to $10. Arkansas Medicaid's rate study concluded that the cost of dispensing a prescription in Arkansas is $5.08. Considering the significantly higher cost of doing business in California, a $6 to $10 per prescription estimate is very realistic. These costs are significantly higher than Medi-Cal's current professional fee of $4.05.
>
> Pharmacy providers have relied on the margin between acquisition cost and the Medi-Cal ingredient cost reimbursement rate to account for the difference in the actual cost of dispensing a prescription and the Medi-Cal rate of $4.05.
>
> The California Pharmacists Association (CPhA) contends that pharmacy providers will be unable to provide prescription services [for] Medi-Cal beneficiaries of the rate proposed in the original May Revision; in some cases, forcing independent pharmacies (non-chain) in areas of high Medi-Cal enrollment out of business. This reduction in pharmacy providers would create access problems for the Medi-Cal beneficiary. CPhA believes that this proposal coupled with the implementation of a broader MAIC program and a reinstatement of the 50-cent claim reduction are

> cuts that the pharmacy provider community will be unable to bear. In recognition of CPhA's contentions, the DHS modified the original May revision proposal to AWP-10% for all drugs.

(Robben Decl., Ex. 35 at 92-93.) The report also noted that the Myers & Stauffer study, which was due on July 1, 2002, was released on August 23, 2002. *Id.* at 93. In the report DHS stated its support for the change. *Id.* at 10-11.

53. The legislation became law on December 1, 2002.

54. In 2004, the California legislature lowered the EAC calculation to AWP minus 17 percent and raised the dispensing fee to $7.25.

55. Originally, DHS had proposed moving EAC to AWP minus 20 percent. (Robben Decl., Ex. 28 at 192:17-193:10; Ex. 36.) In May of 2004, in response to an inquiry from a California Senate Budget Committee staffer, Kevin Gorospe prepared a paper to support the change to AWP minus 20 percent. (Robben Decl., Ex. 28 at 215:20-222:21; Ex. 37.) That document began by noting that, based on confidential discussions with providers and other individuals knowledgeable of provider costs, "it appears that the average pharmacy obtains drugs at Wholesaler Acquisition Cost (WAC) less some percentage that is based on how quickly they pay their invoices . . . The acquisition cost of generic drugs is often lower than this, however, the specific discount was not readily available." (Robben Decl., Ex. 37.) The document indicates that DHS then obtained WAC prices from First DataBank. *Id.* The document then states as follows:

> Based on this information, the Department has determined that the AWP is, on average, 26% higher than WAC for brand name drugs and 350% higher than WAC for generic drugs. Based on this information, if the pharmacies are purchasing brand name drugs between WAC and WAC minus 2% and the Department reimburses the pharmacies at AWP minus 20%, on average, the pharmacies have approximately a 1-3% margin (profit) on brand name drugs and 180-182% margin on generic drugs. Using current AWP and WAC prices and utilization volume from 2003, the

> weighted average margin on drugs would be 3-5%. The overall margin is probably higher because the acquisition cost of generic drugs is likely lower than what is presented in these calculations.

Id. The document also proposes an increase in the dispensing fee to $8.30.

56. In an e-mail dated June 15, 2004, Kevin Gorospe stated that, based on information he had received from pharmacy providers, he believed "that the current proposal of AWP-20% plus $8.30 will be too deep of a cut to maintain access, especially in the area of Long Term Care (LTC)." (Robben Decl., Ex. 38.) At the end of the e-mail, Mr. Gorospe laid out three alternative pricing strategies:

> 1 – Change the rate to AWP-17% + $7.50 – This rate is close to the M&S, though it doesn't allow for inflation of costs in the dispensing fee. It provides a level of savings equal to that proposed by the providers of $42.7 million GF.
> 2 – Leave proposal at AWP-20% + $8.30 and give LTC a fee of $10.30 – This would provide a cushion for the higher cost associated with LTC pharmacy and result in a $74.2 million GF savings in the BY.
> 3 – Change to AWP-18% + $8.30 ($9.30 for LTC) – This provides for a compromise rate between the original proposal and the level at which providers indicate that they stop taking Medi-Cal patients. This is a $41.5 million GF savings in the BY.
>
> DHS staff believe that option 3 is the best. It allows for continued margin and is likely at level to maintain access in the program. It does however result in a decrease in savings of $37.6 million GF in the BY.

Id.

57. A June 16, 2004 e-mail sent from the e-mail account of Bud Lee stated that, based on feedback from pharmacies, the proposed change to AWP minus 20 percent "may unduly disaffect access, particularly for LTC facility patients and pharmacies providing high volumes of innovator drugs." (Robben Decl., Ex. 39.) The e-mail proposed adopting AWP minus 17 percent and an increase in the dispensing fee to $7.50, with an additional 50 cents for long term care pharmacies. *Id.* Under the heading "RATIONALE", the e-mail stated as follows:

> AWP-20% is an arbitrary number, notwithstanding the current proposal from CPhA. AWP-17% is grounded in the Myers and Stauffer study, a rigorous and reliable $400,000 analysis that found the acquisition cost of brand-named drugs on average was AWP-17.2%. This will be the most defensible position in the event of litigation.

Id.

58. The fact sheet that DHS prepared for the legislature concerning the proposal noted that AWP minus 17 percent was still considerably higher than providers' costs for generic drugs. "At AWP-17% Medi-Cal will still be overpaying the cost of generic drugs, which pharmacies can purchase at AWP-40% or less." (Robben Decl., Ex. 36.)

59. The reimbursement methodology proposed in this fact sheet was the one the legislature ultimately adopted. *See supra* at ¶19. It is still in effect today.

VI. THE COMMENCEMENT OF THIS ACTION

60. This action was originally commenced in July of 1998 by a *qui tam* relator, Ven-A-Care of the Florida Keys, Inc ("Ven-A-Care"). (Robben Decl., Ex. 40; Ex. 41 at 2.) The original *qui tam* complaint was filed under seal and named as defendants 23 drug manufacturers, including Dey, Inc. (Robben Decl., Ex. 41 at 2.)

61. The original *qui tam* complaint sets forth a chart containing the published price, Ven-A-Care's acquisition cost, and the so-called "spread," both in percentage and dollar terms, for 11 of Dey's Subject NDCs. (Robben Decl., Ex. 40 at 105-107.) The alleged "spreads" range from 55 percent to over 500 percent. *Id.* Set forth in the chart below are examples of the for 2 of the Dey NDCs:

Drug	**Ven-A-Care's Cost (per package)**	**California's Payment (per package)**	**"Spread"**
Dey's cromolyn 49502068902	$24.50	$39.90	62%
Dey's albuterol sulfate 49502069703	$8.50	$28.74	238%

62. Ven-A-Care filed an amended *qui tam* complaint in August of 2002, also under seal, which named a total of 46 drug manufacturers, including Dey, Mylan, and Sandoz. (Robben Decl., Ex. 42; Ex. 41 at 4.)

63. Like the original *qui tam* complaint, the amended *qui tam* complaint contained charts setting the published price, Ven-A-Care's acquisition cost, and the so-called "spread," both in percentage and dollar terms for 283 of Mylan's NDCs (*id.* at 93-117) and for 17 of Sandoz's Subject NDCs (*id.* at 164). Set forth in the chart below are examples for 2 of the Mylan NDCs and 2 of the Sandoz NDCs:

Drug	**Ven-A-Care's Cost (per package)**	**California's Payment (per package)**	**"Spread"**
Mylan's cimetidine 00378037205	$32.74	$765.68	2239%
Mylan's diphenoxylate/atropine 00378041510	$165.34	$422.75	156%
Sandoz' alprazolam 00781107905	$7.04	$453.74	6345%
Sandoz' fluphenazine HCL 00781143901	$12.71	$109.01	378%

64. The action remained under seal as to Dey, Mylan, and Sandoz, until August of 2005, when California filed its complaint in intervention. (Robben Decl., Ex. 1.)

VII. CHALLENGES TO CALIFORNIA'S REIMBURSEMENT METHODOLOGY

65. On January 16, 2009, a group of pharmacists and other Medicaid providers commenced an action in the United States District Court for the Central District of California entitled *Managed Pharmacy Care v. David Maxwell-Jolly*, No. 09-00382-CAS-MAN. In the action, the providers seek to enjoin the current director of the California Department of Health and Human Services from implementing sections of the legislation AB 1183 that would implement a five percent reduction in pharmacy reimbursement payments to Medi-Cal providers.

(Robben Decl., Ex. 43 at 1-2.) The providers contend that the five percent reduction, the legislature's conduct in enacting it, and the director's conduct in implementing it, are inconsistent with and in violation of federal law governing Medicaid reimbursement payments. (Robben Decl., Ex. 44, at 3-4.) In particular, the providers contend that the five percent reduction violates 42 U.S.C. 1396a(a)(30)(A), which requires that state Medicaid programs make sure that their reimbursement payments are "consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." *Id.*

66. On February 2, 2009, the providers moved for a preliminary injunction to enjoin the five percent rate cut. (Robben Decl., Ex. 44.)

67. On February 11, 2009, Maxwell-Jolly filed an opposition to the providers' preliminary injunction motion. (Robben Decl., Ex. 43.) The opposition papers filed by Maxwell-Jolly include a declaration of Kevin Gorospe. (Robben Decl., Ex. 43; Ex. 45.) The declaration contains the following paragraph in response to contentions in the providers' motion that the current dispensing fee of $7.25 does not accurately reflect the cost of dispensing the drugs:

> Mr. Wilson next alleges that there is a difference between the Medi-Cal dispensing fee and the average Medi-Cal dispensing cost of $4.61 per prescription. Actually the difference between the inflated average dispensing cost per prescription of $11.59 and the 5% reduced Medi-Cal dispensing fee is $4.71. But as explained in at [*sic*] pages 9-10 of the DHCS Analysis, the median dispensing fee cost is $11.01. That means half the pharmacies have a dispensing fee cost [*sic*] below that amount. Obviously then more efficient pharmacies will not have as great a spread between their dispensing cost per prescription and Medi-Cal dispensing fee. More importantly, for each drug dispensed, Medi-Cal pays not only the dispensing fee but also an amount for the drug itself. And

> it is because the Medi-Cal reimbursement for the drug itself frequently is well above pharmacy acquisition cost, that any loss on the dispensing fee portion of reimbursement is made up for by a significant profit on Medi-Cal reimbursement for the drug itself.

Id. at ¶ 21.

68. The court presiding over the case granted the providers' motion for a preliminary injunction on February 27, 2009. (Robben Decl., Ex. 46.)

VIII. FULS ESTABLISHED BY CMS

A. The FULs CMS Set Did Not Comport With the Formula Set Forth in the Regulations

69. As a general rule, CMS did not adhere to the formula prescribed in 42 C.F.R. 447.332 (2006) when establishing FULs.

70. Sue Gaston was the CMS employee responsible for setting FULs from April 1991 through February of 2003. (Robben Decl., Ex. 47 at 40:7-10, 45:2-12.)

71. Gail Sexton was the CMS employee responsible for setting FULs beginning in November, 2004. (Robben Decl., Ex. 48 at 49:13-50:21.)

72. Although Ms. Gaston and Ms. Sexton were only examined on nine drugs that were selected for targeted FUL discovery, Ms. Sexton testified those nine drugs are not unique, and that the process used to set the FULs for these drugs is representative of the process for establishing FULs more generally. (Robben Decl., Ex. 48 at 31:4-22, 33:1-9.)

73. Ms. Gaston and Ms. Sexton testified that CMS used a computer program ("the FULs System") to gather both Orange Book data and pricing data from the three national compendia and to initially calculate FULs for those drugs that met the specified criteria. Then, CMS officials would engage in a "manual review" process because "we want to make sure that that lowest price is a true price." (Robben Decl., Ex. 47 at 232:22-241:7; Robben Decl., Ex. 12 at 410:14-411:18, 416:10-15, 429:18-22, 432:14-21, 533:5-10; Robben Decl., Ex. 48 at 89:2-5,

93:12-94:13 (stating that Ms. Sexton conducted "further manual interventions" into the FUL for albuterol – one of the Subject Drugs – because she had "learned of other suppliers that were marketing this drug"); *id*. at 95:15-95:20 (stating that she would conduct a manual review "in cases where I saw that manual intervention could have changed the price, changed the federal upper limit, or where it appeared that perhaps the criteria was not met and that further intervention should have been taken"); *id.* at 138:6-7 ("When possible we would manually verify that drugs were available."); *id.* at 147:8-15 (stating that upon finding "an outlier situation" she would "do some manual verifications on whether that NDC was available and available at that price")).

74. Ms. Gaston further testified that the manual review was used to determine whether a drug was "truly available or not" and whether or not "you should follow up and see if it's available." (Robben Decl., Ex. 47 at 229:8-230:14.)

75. During her deposition, Ms. Gaston was presented with the 2001 FULs System printout for clonazepam, one of the Subject Drugs, on which someone had crossed out the FUL generated by the FULs System, $0.1199, and written in a different, higher FUL, $0.2455. (Robben Decl., Ex. 12 at 441:22-443:4 & Ex. 5.)

76. Ms. Gaston testified that the lowest published price was not used when setting the FUL for clonazepam because CMS "wanted to make sure that the FUL price that's set is a reasonable price and that we'll be assured the availability of the drug" and that therefore "we went up to the next lowest price." (Robben Decl., Ex. 12 at 442:21-445:4.)

77. During her deposition, Ms. Gaston was presented with the 2001 FULs System printout for lorazepam, another Subject Drug, on which someone had crossed out the

FUL generated by the FULs System, $0.2999, and written in a different, higher FUL, $0.5718. (Robben Decl., Ex. 12 at 445:14-450:20 & Ex. 6.)

78. Ms. Gaston testified that CMS used a price other than the lowest published price for lorazepam as the basis for the FUL to ensure that the FUL was set at a "reasonable" level. (Robben Decl., Ex. 12 at 450:6-453:1.)

79. During her deposition, Ms. Gaston was presented with the 2001 FULs System printout for cefadroxil, on which someone had crossed out the FUL generated by the FULs System, $1.2749, and written in a different, higher FUL, $2.9000. (Robben Decl., Ex. 12 at 453:12-454:20 & Ex. 7.)

80. Ms. Gaston testified that the FUL for cefadroxil that had been calculated by the FULs System required "some manual review" because the price on which it had been based "seemed much lower than all the other published prices." (Robben Decl., Ex. 12 at 455:6-12.)

81. During her deposition, Ms. Gaston was presented with the 2001 FULs System printout for metoprolol tartrate, another Subject Drug, which showed a FUL generated by the FULs System of $0.0816 and a handwritten notation that the "new FUL" was $0.0914. (Robben Decl., Ex. 12 at 419:18-22 & Ex. 2.)

82. Ms. Gaston testified that CMS did not use a lower published price to calculate the FUL for metroprolol tartrate because it had discovered that the manufacturer that had reported that lower price was "temporarily out of stock" and that a FUL resulting from that price "might not be a realistic price." (Robben Decl., Ex. 12 at 425:15-427:20.)

83. Ms. Sexton testified that, in February of 2005, the FULs System calculated a FUL for lorazepam, another Subject Drug, based on a published price of $0.077, but that Ms.

Sexton chose not to change the previous FUL, which had been based on a published price of $0.3812. (Robben Decl., Ex. 48 at 126:14-128:11.)

84. Ms. Gaston testified that when she was setting FULs, she could base FULs on B-rated drugs, rather than A-rated drugs, as long as three A-rated drugs were listed in the Orange Book. (Robben Decl., Ex. 12 at 523:15-524:11, 525:8-13.)

85. Ms. Sexton testified that, when she set a FUL for a particular drug, she would consider drugs that were not listed as A-rated in the Orange Book, and set the FUL according to that price. (Robben Decl., Ex. 48 at 104:4-18) (regarding the FUL for the 90 mcg. albuterol inhaler, a Subject Drug).

86. Ms. Gaston testified that when CMS set the FUL for cefadroxil, the FUL was not based on the most common package size. (Robben Decl., Ex. 12 at 466:19- 469:14) (recognizing that while the most common package size was found to be the 100-count of cefadroxil, the FUL had been set on the 50-count package size).

87. Ms. Sexton testified that, when she set the FUL for isosorbide mononitrate, a Subject Drug, she called the manufacturer to determine their unpublished WAC price and set the FUL according to that information. (Robben Decl., Ex. 48 at 113:20-113:21, 117:12-118:3.)

88. Ms. Gaston testified that CMS removed the FUL for the 90 MCG albuterol inhaler upon learning of a shortage of the drug's raw material because "if the product is not available then it wouldn't make sense to put a FUL price on it." (Robben Decl., Ex. 12 at 470:7-472:21.)

89. Ms. Gaston testified that CMS officials would not use a particular published price if that manufacturer "only distribute[d] to maybe [a] limited amount of states and not all states." (Robben Decl., Ex. 12 at 429:9-17.)

90. CMS officials would decline to set a FUL when the FUL was equal to an AWP because States' "regular reimbursement methodology would be a percentage off of AWP," such that setting a FUL that was equal to AWP "would kind of counter what the states were doing with their other reimbursement methodology." (Robben Decl., Ex. 12 at 456:10-20 (discussing the FUL for cefadroxil); *see also* Robben Decl., Ex. 48 at 76:20-77:13 (stating that she could not recall ever having set a FUL based on an AWP). Ms. Gaston testified that CMS "wouldn't have used AWP" when establishing FULs because "[s]etting a FUL using the AWP wouldn't achieve the cost savings." (Robben Decl., Ex. 12 at 458:15-459:7; *see also* Robben Decl., Ex. 48 at 58:15-59:8 ("[I]f the federal upper limit, once it was calculated, was higher than the AWP price or the majority of the AWP prices, then we would generally not set a FUL on those drug ingredients, because the AWP – well, a couple years ago the average AWP on a national basis was I think AWP minus 12 percent for drug reimbursement, estimated acquisition costs for drug reimbursement for a drug that did not have a federal upper limit.")).

91. CMS did not have any written policy in place for employees to follow in setting FULs, and CMS officials individually made decisions about whether and at what rate to set a FUL on a case-by-case basis. (Robben Decl., Ex. 47 at 250:2-6, 252:3-20; Robben Decl., Ex. 12 at 464:7-465:16; Robben Decl., Ex. 48 at 60:22-61:7.)

92. Based on FDA data, ipratropium bromide inhalation solution was qualified to be considered for inclusion on the FUL list in 2000, but was not added to the FUL list until August 24, 2003. (Robben Decl., Ex. 12 at 539:19-545:7; Robben Decl., Ex. 49 at ii.)

B. CMS Set FULs To Strike a Balance Between Cost-Savings and Access

93. CMS officials were informally taught by other CMS officials how to exercise their discretion to set FULs manually so as to meet the dual objectives of cost savings and access. (Robben Decl., Ex. 47 at 225:16-226:7; Robben Decl., Ex. 48 at 73:14-74:22.)

94. When asked about CMS's objectives when establishing FULs, Sue Gaston testified as follows:

> Q. So what we see in Exhibit 6 is another situation in which, exercising its discretion, CMS chose to set a FUL not based on the lowest published price but based on the next lowest published price because that's what was reasonable to do in terms of ensuring access, correct?
>
> A. Correct.

(Robben Decl., Ex. 12 at 451:12-19.)

95. Ms. Gaston further testified as follows:

> Q. So as we've kind of seen throughout, CMS is trying to establish a FUL that's not too low and not too high to achieve a cost savings, but also not set it too low to create an access issue; that's the balance CMS is trying to strike?
>
> A. Correct.
>
> Q. And you did that – the balance was struck, sometimes the computer program worked as it was supposed to and that balance was struck by the computer program, but other times it was the result of manual intervention?
>
> A. Correct.
>
> Q. And the manual intervention resulted in CMS making a choice in its discretion, correct?
>
> A. Correct.

(Robben Decl., Ex. 23 at 498:16-499:9.)

C. CMS Reviewed Market Information When It Set FULs

96. Pursuant to federal law, all drug manufacturers whose drugs are reimbursed under state Medicaid programs must enter into a rebate agreement (the "Rebate Agreement") with the United States Secretary of Health and Human Services, and report Average Manufacturer Prices ("AMPs") to CMS on a quarterly basis. *See* 42 U.S.C. § 1396r-8(a)(1), (b)(3)(A). The Rebate Agreement sets forth a comprehensive definition of AMP as an average of the discounted unit price of a drug:

> (a) "Average Manufacturer Price (AMP)" means, with respect to a Covered Outpatient Drug of the Manufacturer for a calendar quarter, the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid. It is calculated as a weighted average of prices for all the Manufacturer's package sizes for each Covered Outpatient Drug sold by the Manufacturer during that quarter. Specifically, it is calculated as Net Sales divided by numbers of units sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements). For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(Robben Decl., Ex. 50, at § I(a) (Enclosure A).) Each of the capitalized terms incorporated in the AMP definition set forth above is further defined by the Rebate Agreement. (Robben Decl., Ex. 50, at § I.)

97. Ms. Gaston testified that she had access to the AMP information that manufacturers reported to CMS. (Robben Decl., Ex. 12 at 528:1-3 ("Q. Would you have had access to that AMP information? A. Yes.").

98. CMS officials received feedback from members of the pharmacy community and from State Medicaid agencies about "whether they felt that the FUL prices or the drugs were correctly on the FUL list or needed [to be] adjust[ed]"; whether the product was "available"; and whether "the pricing appears to be either too low or too high." (Robben Decl., Ex. 12 at 433:14-434:8, 435:8-11; *see also* Robben Decl., Ex. 48 at 110:14-21 (stating that in addition to feedback from industry groups, she received feedback "from pharmacy providers or states")).

99. In response to feedback that a drug was not available, CMS officials would "call the manufacturer or wholesaler and verify if that was a fact." (Robben Decl., Ex. 12 at 435:12-21; *see also* Robben Decl., Ex. 48 at 111:12-17 (stating that in response to feedback, Ms. Sexton "would look at the availability in the compendia" or "call suppliers")).

100. CMS officials telephoned drug manufacturers, wholesalers, or a compendia publisher when the databases did not provide the WAC for a particular NDC or to determine whether a drug was available. (Robben Decl., Ex. 48 at 60:22-61:7 ("There were times when we would call or I would call the manufacturers or the suppliers to determine if a drug was available. . . . [S]ome of these drugs were looked at, most of them, on a case-by-case basis because there were times when we would have three or more suppliers but perhaps we were missing a wholesale acquisition cost, for instance."); *id.* at 60:12-16 ("[I]f you just looked at the prices that were on the pricing sheet and there was a wholesale acquisition cost that was missing, that could have had a lower wholesale acquisition cost than the prices that were shown . . . "); *id.*

at 116:1-116:14 ("So to determine whether there was a lower WAC out there, that looks like that was the impetus for the calls.").

101. Ms. Gaston testified that she would sometimes review state MAC prices to "verify that the FUL price that we establish is in the ballpark" and "looks realistic for states." (Robben Decl., Ex. 12 at 478:17-479:9.)

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on November 25, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Sarah L. Reid
Sarah L. Reid